

PUBLIC COMMENT FOR CONSIDERATION BY THE NATIONAL ORGANIC STANDARDS BOARD  
PROPOSING CRITERIA FOR DETERMINING AGRICULTURAL AND NON-AGRICULTURAL  
SUBSTANCES FOR USE IN ORGANIC PROCESSED PRODUCTS

SUBMITTED BY:  
OREGON TILTH CERTIFIED ORGANIC (OTCO)

**Introduction**

In response to the growth of the organic food industry, food companies are producing new and improved products to meet market demand, as well as the requirements of the National Organic Rule. As a result, ingredients currently listed as nonagricultural substances in §205.605 of the National List, such as flavors, colors, and yeast are entering the market as organic, and ingredients that share seemingly similar characteristics as substances listed on §205.605, such as malic acid and inulin, are being approved as non-organic agricultural ingredients.

As a leading certifier of organic processed products, Oregon Tilth staff has been faced with the challenge of reviewing many of these new emerging substances. In each case, it has been extremely challenging to determine whether the substance would fall under the definition of an "agricultural product", or under the definition of a "non-agricultural substance", as defined in §205.2 of the National Organic Rule. Close examination of these definitions, in conjunction with substances already identified as non-agricultural via their listing in §205.605, led us to the conclusion that the definitions in the rule in and of themselves do not provide clear guidelines with which to consistently evaluate a substance.

In response to this challenging topic and to help aid in the decision process, Oregon Tilth staff has designed a Decision Tree. The Decision Tree is meant to provide a standardized and transparent evaluation tool to ensure consistency among certification agencies and the organic industry. Adoption of criteria for distinguishing agricultural from non-agricultural substances has important implications including:

- determining what substances must be reviewed by the National Organic Standards Board (NOSB) for allowance as non-agricultural ingredients in processed foods,
- determining what types of products are eligible for organic certification, and
- identifying minor agricultural ingredients not yet commercially available in an organic form, thereby prompting innovation/developments in food technology to meet the demands for such minor ingredients in an organic form.

OTCO is submitting proposed criteria for distinguishing agricultural from nonagricultural substances for consideration by the NOSB. Attached is the Decision Tree and accompanying narrative that explains the issue, the basis for the questions in the Decision Tree, definitions to support the terminology used in the Decision Tree, and several examples of substances evaluated using the criteria set forth in the Decision Tree. The Decision Tree has already been shared with cooperating West Coast Certifiers. Their comments are attached at the end of this document. OTCO appreciates the opportunity to present this proposal and invites comments, criticisms, and suggestions for its improvement.



## Criteria for Determining Agricultural and Nonagricultural Substances for Use in Organic Processed Products

### Summary of the Issue

The NOP Final Rule requires that a substance used in organic processing or handling be either: 1) organically produced; 2) non-agricultural and appearing on the National List at section §205.605; or 3) agricultural, determined to be not commercially available in organic form, and used as provided for in §205.606. The distinction between whether a substance is agricultural, or whether it must be on the National List as a permitted non-agricultural substance is subject to the definitions of 'agricultural product' and 'nonagricultural substance' defined in §205.2 of the Final Rule.

An **agricultural product** is defined as "any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption". This broad definition alone, would allow for use of any number of substances derived from an agricultural product, so long as they are not produced using prohibited practices specified in the appropriate sections of the rule.

A **nonagricultural substance** on the other hand is defined as "a substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction". This definition is ambiguous and lends itself to more questions than answers.

The example of a bacterial culture not being a product of agriculture, raises the question of whether this example refers to microbial cultures in general. If so, how do organic mushrooms and organic yeast, both of which are commercially available, fit into the definition?

The concept that an ingredient, product, or substance is no longer agricultural once it has been processed into an extract, isolate, or fraction is nearly impossible to evaluate, and is not consistent with many of the agricultural products currently on the market. Most processing activities render the finished products as unrecognizable from their original raw materials. Substances that are clearly recognized as agricultural products, such as maltodextrin, cornstarch, rice syrup, and vegetable protein, could all be classified as non-agricultural according to this definition of 'nonagricultural'. Without further definition or specification of the terms "identity" and "unrecognizable", evaluation of a substance is difficult at best. Furthermore, the example of pectin and gums as non-agricultural substances is confusing, because both of these substances are also listed as agricultural ingredients in §205.606.

The lack of clear criteria is causing inconsistent decision making among the various certification agencies. As a result, ingredients such as malic acid, stearic acid, and inulin are finding their way onto the ingredient panels of organic products, (approved as minor agricultural ingredients commercially unavailable in organic form), while the criteria used to determine their classification as 'agricultural' is not transparent. Furthermore, the NOSB could spend an unwarranted amount of time reviewing substances for inclusion on the National List, only to discover that the substance(s) were considered by the NOP as 'agricultural' and therefore not subject to review.

Developing agreed upon criteria by which to distinguish agricultural from nonagricultural substances is paramount given the above situation, and the rate at which the organic market is expanding. As the food

industry responds to the growing demand for healthy and organic food, so does processing technology.

Research, innovative techniques, and advanced technologies are turning out new and improved minor ingredients to enhance the flavor, nutrition, and general quality of a product. And, as new organic products in nearly every food category rapidly enter the market, so will the array of new minor ingredients that will need to be evaluated as either agricultural or nonagricultural.

To aid in the process of distinguishing agricultural from nonagricultural substances, OTCO has designed a Decision Tree. The Decision Tree is based, for the most part, on the definitions and rules explicitly stated in the NOP Final Rule. Any interpretation of the rule is based on common sense or the precedent of products already existing in the marketplace. A list of definitions has also been established to support the terminology used in the Decision Tree. All other applicable requirements of the NOP Final Rule are assumed, such as prohibition of excluded methods and ionizing irradiation.

### **Narrative Explanation to Accompany Decision Tree Questions**

Questions on the tree are in italics; non-italicized text is descriptive; capitalized text refers to criteria based on interpretation for which comment is solicited.

1. *Can the substance in question be recognized as a product or component derived from an agricultural product (plant, animal, or fungus grown on an agricultural substrate)?* The word 'recognized' shall encompass a full range of characteristics by which a thing is recognizable or known (i.e. chemical analysis, sight, smell, past experience). An agricultural product must be recognizable according to the definition in section §205.2 and is limited to plants and animals. **IN ADDITION TO PLANTS AND ANIMALS, FUNGI ARE ALSO INCLUDED BECAUSE MUSHROOMS, WHICH ARE FUNGI, HAVE BEEN TRADITIONALLY AND WIDELY ACCEPTED AS AGRICULTURAL PRODUCTS.** Minerals and bacterial cultures are not considered products of agriculture, as specified in the National Rule.
2. *Is the substance a metabolic product isolated from a microbial culture?* Substances such as citric acid, sugar alcohols (i.e. xylitol, erythritol), glutamic acid, and xanthum gum can all be produced as byproducts of microbial fermentation, where a particular kind of microorganism is grown using appropriate substrates. One of the major requirements for the growth of an organism is a carbon source, of which the cheapest source happens to be agricultural (i.e. crude sugar made from corn). Despite the significant amount of agricultural material used in the process, it is the growth of the organism that is responsible for the actual production of the substance in question. The substance therefore is more a microbial product, than an agricultural product. A distinction can be made between this type of process and the production of mushrooms, for example, in that the mushrooms have been grown on an agricultural medium and are harvested to constitute the final product.

**Note: The definition of 'synthetic' and 'nonsynthetic' have been applied to questions 3, 4, and 5.**

3. *Has the substance been processed to the extent that its chemical structure has been changed (decomposed, re-arranged, or added to) from its naturally occurring state?* Question #2 begins to address whether the substance is synthetic or nonsynthetic, operating under the premise that if the substance is synthetic, then the identity of the agricultural product from which the substance is derived would not be recognizable due to the loss (i.e. change in chemical structure) of its original identity.

It should be noted that, in 1997 when the Department published the first NOP Proposed Rule, it determined that unmodified cornstarch was an "agricultural product". The Department, in the preamble to the first Proposed Rule, stated, "Unmodified starches are agricultural ingredients because they are manufactured from agricultural products through methods that do not meet the Act's definition of

synthetic. Their use would therefore be permitted as non-organic agricultural ingredients in proposed §205.27.” (62 Fed-Reg. 65894, Dec.16, 1997).

**Note: The next two questions address the process by which the chemical change occurred, and which processes should be accepted despite the chemical change.**

4. ***Does this change include chemical treatments?*** Continuing from question 3, this question eliminates any substance that has undergone a chemical change during processing as a result of chemical treatments. This elimination is based on the definition for 'synthetic' provided in §205.2 which assumes that as soon as a substance is classified as 'synthetic', it loses its 'agricultural' status.
5. ***Is the change in chemical structure a result of a naturally occurring biological process, such as fermentation or enzymatic hydrolysis, OR A RESULT OF A MECHANICAL/PHYSICAL PROCESS?*** The definition of 'synthetic' in section §205.2 of the National Rule, allows for a substance to be chemically changed and retain a nonsynthetic status, if the change was created by naturally occurring biological processes. In addition to biological processes, the Decision Tree allows for chemical changes which result from physical processes such as cooking and steam distillation. Cooking, for example, may result in the breaking or formation of covalent bonds which are chemical changes. A cake, or loaf of bread however, are not thought of as synthetic products. While the biological process referred to in the definition of 'synthetic' may refer to naturally occurring processes, the process in actuality will be employed by the manufacturer, just as the heat or steam would be applied. And, the chemical change that can be brought about using physical methods is often less significant than changes caused by biological methods.

## **Definitions**

**Agricultural product** - Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

**Bacterial Culture** –A specific kind of bacterium grown on or in a media.

**Chemical Change** – A change in which new substances with new properties are formed due to the rearrangement, combination, or separation of atoms, generally involving breakage or formation of covalent bonds.

**Chemical Process** - (Chemistry) any process determined by the atomic and molecular composition and structure of the substances involved.

**Chemical Treatment**- Process wherein a chemical compound is added which chemically reacts with the substance it has been added to.

**Enzymatic Hydrolysis** - A process by which enzymes (biological catalysts) are used to break covalent bonds such as the conversion of starch or cellulose into sugar, or proteins into amino acids.

**Microbial preparation** – A specific kind or kinds of microorganism(s) grown on or in a media.

**Nonagricultural Substance** - A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from,

or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

**Nonsynthetic (natural)** - A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

**Processing - Mechanical or biological methods**, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

**Synthetic** - A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes. **Note:** Separating, distilling, extracting, canning, cooking, baking, and fermenting can result in a chemical change where compounds are formed or decomposed.

**Substrate** – The portion of the media metabolized by an organism.

### **Decision Tree Examples**

The following examples are provided primarily to address questions that have come up during the process of creating the Decision Tree and to solicit comment. It is important to note that there are several different methods for manufacturing the chosen examples. Adoption of the Decision Tree will require that substances be evaluated on a case-by-case basis using detailed process information supplied by the manufacturer. In some examples, a general process flow was chosen. In others, a specific process flow was chosen.

**Citric Acid** – Citric Acid is currently listed at section 9205.605 of the National List as a nonsynthetic, nonagricultural substance. A basic process flow was used.

1. Not likely. Citric acid is a tricarboxylic acid first isolated from lemon juice and crystallized in 1784. It is abundant in fruits, particularly citrus fruits. Until the early nineteenth century most citric acid was produced from lemon, although it was recognized as a major metabolic product of fungal species such as *Penicillium* and *Mucor*. Today, most citric acid is produced from fungal fermentations. The raw material is usually sugar or molasses, which comprises the majority of the materials used to grow the fungi. The citric acid however is a metabolic byproduct of the fungal fermentation.  
= **Non-agricultural substance**

**Note: if the citric acid were isolated from a lemon and its chemical structure had not been changed, except as a result of a naturally occurring biological process or a mechanical/physical process, it could then be considered an agricultural substance.**

**High-methoxy pectin** – Pectin is listed on the National List at section 9205.605 as low-methoxy, and at section 9205.606 as high-methoxy. Commercial pectin is obtained from citrus peel and apple pomace. Pectin from lemon and lime peel is the easiest to isolate and is of the highest quality. By definition, preparations in which more than half of the carboxyl groups are in the methyl ester form are classified as high-methoxyl pectins. Preparations in which less than half of the carboxyl groups are in the methyl ester form are called low-methoxyl pectins. The percentage of carboxyl groups esterified with methanol is the degree of esterification. Treatment

of a pectin preparation with ammonia dissolved in methanol converts some of the methyl ester groups into carboxamide groups. In the process, a low methoxyl pectin is formed. It can be assumed that the treatment necessary to form low-methoxyl pectin resulted in the dual listing of this substance. A basic manufacturing process for high-methoxy pectin was used to test the 'agricultural' form.

1. Yes. The raw material is apple pomace. Proceed to question #2.
2. No. Pectin is extracted from apple pomace. Proceed to question #3.
3. No. The pectin is separated from other components of the cell wall by partial or mild acid hydrolysis. The acid hydrolysis does not however hydrolyze the bonds between the galacturonic acid residues that make up pectin.  
= Agricultural substance

**Stearic Acid** – Stearic acid occurs naturally in some vegetable oils, cascarilla bark extract, and as a glyceride in tallow and other animal fats and oil. It is a major ingredient used in making bar soaps and lubricants. This particular example is for the use of stearic acid as a lubricant in the manufacture of tablets and capsules (processing aid). A specific manufacturing process was used.

1. Yes. Stearic acid is a fatty acid, derived from edible palm oil using a fractionation process. Proceed to question #2.
2. No. Stearic acid is naturally occurring in palm oil as a triglyceride, composed of fatty acids and glycerine. Proceed to question #3.
3. Yes. The level at which a chemical change has occurred is the hydrolysis and fractionation of a triglyceride into free fatty acids and glycerine. Proceed to question #4.
4. No. The substance is not manufactured using a chemical process. Proceed to question #5.
5. Yes. The stearic acid product is manufactured using steam distillation (steam extraction and condensation) to split and fractionate the fatty acids, followed by physical manipulation (spray-drying) in conjunction with cooling to produce beaded stearic acid. The beads are then ground using a steel mill to micronize the product. Furthermore, the fatty acid isolate has not been chemically modified. Proceed to box #6.
6. Agricultural substance

**Inulin & Oligofructose** (commonly used together as a product) – Inulin is a term applied to a heterogeneous blend of fructose polymers found widely distributed in nature as plant storage carbohydrates. Oligofructose is a subgroup of inulin. Inulin is scientifically proven to increase the activity of live cultures (beneficial bacteria) and to help prevent the growth of harmful bacteria in the digestive tract. Inulin is used as good source of soluble dietary fiber and is well suited for diabetics because it does not increase the glucose level or insulin level in the blood. Research has also shown that inulin significantly increases the absorption of calcium. This substance is being used in organic dairy products currently in the market place. A basic manufacturing process was used.

1. Yes. The inulin was extracted from chicory roots, which contain approximately 15-17% inulin. Go to question #2.
2. No. The inulin is extracted from the chicory root. Proceed to question #3.
3. Yes. The inulin is partially hydrolyzed. In other words, linear chains of fructose units are broken into smaller chains. Proceed to question #4.
4. No. The manufacturing process for inulin is rather similar to that of sugar extracted from sugar beets. The roots are typically harvested, sliced and washed. Inulin is then extracted from the root by using a hot water diffusion process. No other chemical treatments are used. Go to question #5.
5. Yes. The inulin is subjected to partial enzymatic hydrolysis. Go to box #6.
6. Agricultural substance

**Yeast** – Yeast will be an agenda topic at the National Organic Standards Board meeting in Washington D.C, October 12-14, 2004. A request will be made to change the classification of yeast from a 'nonagricultural (nonorganic) substance' to an 'agricultural product'. A specific manufacturing process was used.

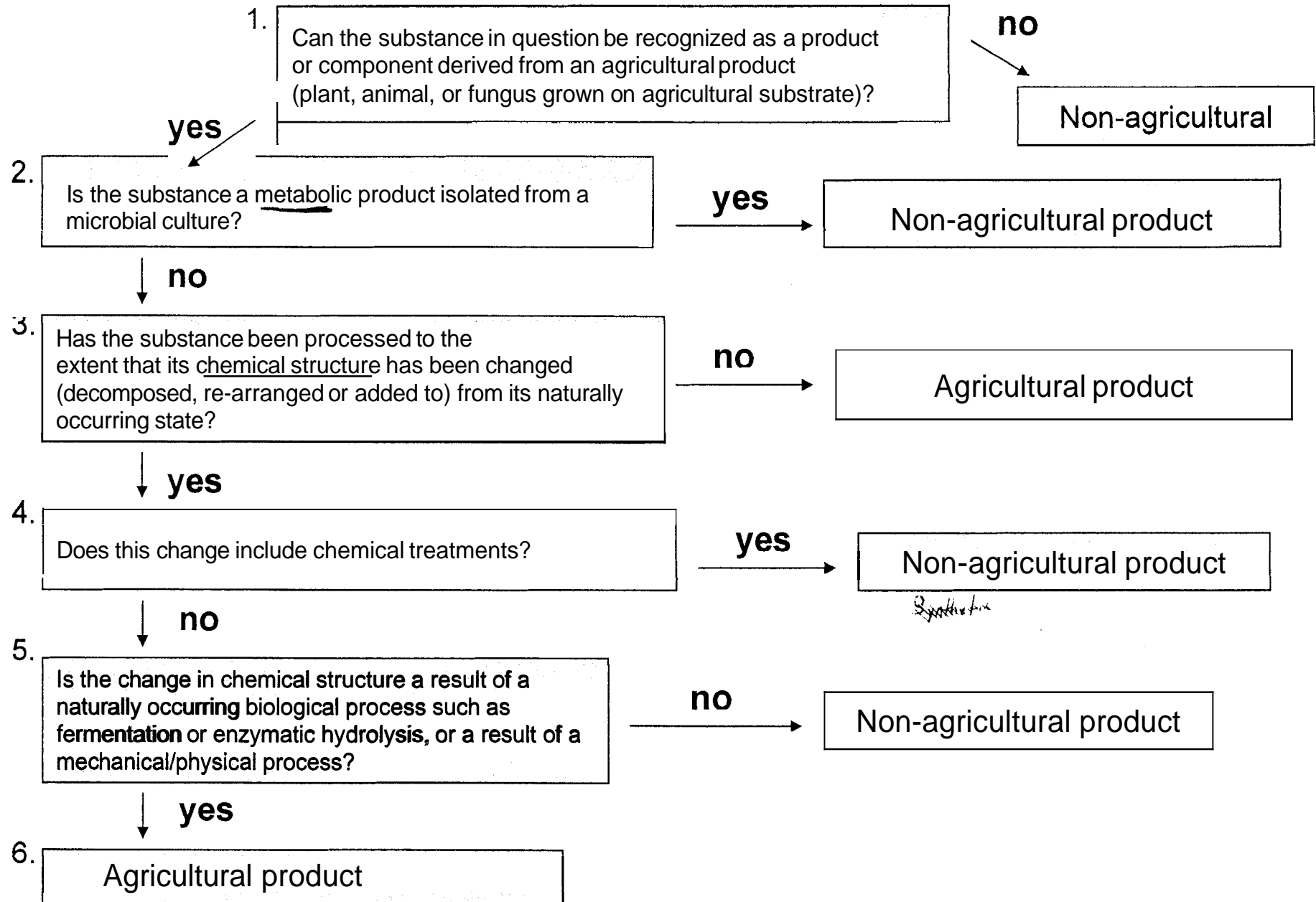
1. Yes. The manufacturing process for yeast can be likened to farming mushrooms –preparation, seeding, cultivation and harvesting. Unlike mushrooms however, yeast is grown in highly automated, temperature-controlled stainless steel fermenters. The preferred source of carbohydrates for yeast is sugar, usually from molasses (sugar beets) or cane sugar. The yeast (a fungus) is grown on an agricultural substrate.
2. No. The yeast itself is harvested. The harvesting is nothing more than concentrating and washing the yeast cells by passing the fermented liquid through large centrifugal pumps called separators. Proceed to question #3.
3. No. The yeast remains unchanged. The quantity has simply been increased.  
= **Agricultural substance**

### **CONCLUSION**

The objective of the Decision Tree is to provide guidelines with which to initially evaluate a substance at a fairly detailed level. The criteria presented in the tree can be broken down into two basic ideas: 1) In order for a substance to be considered agricultural, the substance must come from a plant, animal, or fungus grown on an agricultural substrate; 2) If the substance has been processed from an agricultural product it must not undergo a chemical change, unless that chemical change was created by a naturally occurring biological method, or by a mechanical/physical method.



## Criteria for Determining Agricultural vs. Non-agricultural Substances for Use in Organic Processed Products







STATE OF WASHINGTON

DEPARTMENT OF AGRICULTURE

P.O. Box 42560 • Olympia, Washington 98504-2560 • (360) 902-1800

October 8, 2004

On behalf of Washington State Department of Agriculture (WSDA), I have reviewed OTCO's Criteria for Determining Agricultural versus Non-agricultural Products dated September 29, 2004.

WSDA is in agreement with Janning Kennedy from CCOF, and supports OTCO's efforts and proposal. WSDA also recognizes the need for creating guidelines and a standard technique for evaluating substances to ensure consistency throughout certification agencies, and the organic industry.

My review is based solely on the substances included in OTCO's example, however, I feel the decision tree is a valid approach for determining agricultural and nonagricultural products. The decision tree should be considered a useful tool that could lead to standardized, clear decisions regarding the classification, and subsequent approval or prohibition of a substance used in organic production or handling.

If you have any questions, I am available at (360) 902-2090, FAX (360) 902-2087, email: [bbook@agr.wa.gov](mailto:bbook@agr.wa.gov).

Sincerely,

Brenda Book  
Organic Program Specialist

cc:\test\42560\p42560\documents\wmsa04\user\databased\attach\bookletter\_041008.doc





# CCOF

*Certification Services, LLC*

September 5, 2004

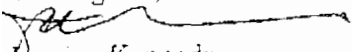
Chris Schreiner  
OREGON TILTH, INC.  
470 Lancaster Drive NE  
Salem, OR 97301

Dear Chris,

Brian McElroy and I reviewed and discussed Oregon Tilth's "Criteria for Determining Agricultural vs. Non-agricultural Products" this afternoon, and CCOF supports your effort. While we have only reviewed it via the substances included in your examples, on the whole it seems to be a reasonable and transparent method for distinguishing between agricultural and nonagricultural products. We note there are some drawbacks in regards to the technical expertise and information required to use it; however a food science background is an unavoidable prerequisite for this level of review.

CCOF believes the need for standardization of decision-making in regards to distinguishing between agricultural and nonagricultural substances is self-evident. This decision tree is potentially a very useful tool for the NOSB and other bodies that could lead to standardized, transparent decisions regarding substance approval or prohibition. We believe the decision tree should be reviewed independently and, assuming no major flaws are found, adopted by organic regulators, certification agents, and other parts of the organic industry that review substances.

Best regards,

  
Janning Kennedy  
Director of Handler Certification  
CCOF

